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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,829	05/09/2002	Yongwon Choi	600-1-200NCIP2	6562

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MORGAN, LEWIS & BOCKIUS LLP  
1701 MARKET STREET  
PHILADELPHIA, PA 19103-2921

EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/873,829

**Applicant(s)**

CHOI ET AL.

**Examiner**

Janet L. Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-17 and 19-86 is/are pending in the application.
- 4a) Of the above claim(s) 9-15,26,28-36 and 38-86 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,16,17,19-21 and 24 is/are allowed.
- 6) ☒ Claim(s) 22, 23, 25, 27, 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

H/C

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 3 January 2005 is acknowledged. Claims 1, 2, 9-17, and 19-86 are pending in this application. Claims 1, 2, 16, 17, 19-25, 27, and 37 are under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to claims 25, 27, and 37 as encompassing non-elected subject matter is withdrawn in response to Applicant's amendment.
3. The rejection of claim 37 under 35 U.S.C. 112, first paragraph, as lacking enablement for pharmaceutical compositions is withdrawn in response to Applicant's provision of post-filing date evidence supporting a therapeutic use.
4. The rejection of claims 2, 3, 5-8, and 16-24 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in response to Applicant's amendment.
5. The rejection of claims 1-8 and 16-23 under 35 U.S.C. 102(a) as anticipated by Anderson et al. is withdrawn in response to Applicant's amendment.
6. The rejection of claims 1-8 and 16-24 under 35 U.S.C. 102(e) as anticipated by the '213 patent is withdrawn in response to Applicant's amendment.
7. The rejection of claims 4-8 and 18-24 under 35 U.S.C. 102(e) as anticipated by the '678 patent is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained***

8. The rejection of claims 22 and 23 under 35 U.S.C. 101 is maintained for reasons of record in the office action of 30 September 2004.

Art Unit: 1646

Applicant has argued that the cells are modified *in vitro*. However, what was stated in the previous office action was that, since there is no requirement that they be isolated, they encompass patients such as gene therapy patients in which they have been used. Previous *in vitro* modification would not alter such circumstances.

9. The rejection of claims 25, 27, and 37 under 35 U.S.C. 102(e) as anticipated by the '213 and '678 patents is maintained for reasons of record in the office action of 30 September 2004.

These claims are drawn to sequences comprising anti-sense TRANCE nucleic acids, modified by phosphodiester analogues in claims 25 and 27. According to the specification (p. 4, lines 27-30), TRANCE nucleic acids include those that encode the polypeptides of SEQ ID NO: 2. Thus these claims are still anticipated by the '213 patent, which teaches a nucleic acid that encodes SEQ ID NO: 2 and teaches antisense molecules. They are also anticipated by the '678 patent because SEQ ID NO: 6 contains many regions identical to instant SEQ ID NO: 1. Antisense agents derived from those regions would be identical to ones derived from the instant sequence.

CLAIMS 1, 2, 16, 17, 19-21, AND 24 ARE ALLOWED. CLAIMS 22, 23, 25, 27, AND 37 ARE REJECTED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1646


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
19 March 2005

  
**JANET ANDRES**  
**PRIMARY EXAMINER**